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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,539	10/16/2003	Kevin T. Foley	5074A-000067	7710

27572 7590 03/17/2008

HARNESS, DICKEY & PIERCE, P.L.C.
P.O. BOX 828
BLOOMFIELD HILLS, MI 48303

EXAMINER	
KISH, JAMES M	

ART UNIT	PAPER NUMBER
3737	

MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,539	FOLEY ET AL.	
	Examiner	Art Unit	
	JAMES KISH	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17,18,20-73 and 75-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,17,18,20-73 and 75-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-15, 17-18, 20-73 and 75-77 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15, 17-18, 22-30, 33-44, 47-73 and 77-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley et al. (US Patent No. 6,226,548) in view of Ellis (US Patent App. No. 2003/0011624).

1. **Claims 1-3 and 78:**

In an alternative interpretation of Claim 1, Foley describes a system that uses at least six separate pedicle screws 250 as shown in Figures 12 and 13. One of these is considered the first member. This first member is illustrated in Figure 7A as having a fastening portion 250 and an engageable portion (represented by the slots removed from the head of the screws). Second member is illustrated in Figure 8 as item 360. The third member is illustrated in Figure 8 and is represented by the unlabeled fasteners that are protruding upward from the head of the first member

250 and simultaneously through second member 360. A localization element is found in Figure 7. Detection unit 110 of Figure 1 comprises an optical tracking unit along with processor 114. The localization element provides navigational information for all three members.

However, Foley provides an image based procedure. Ellis teaches that current methods for computer-assisted interventions are based on one of four paradigms. Three out of four of these paradigms are image-based procedures. The remaining one paradigm is an imageless procedure in which tools and tracking devices are attached to a patient in order to guide the intervention free of imaging. See paragraphs 3-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform an imageless procedure, as taught by Ellis, as a well-known alternative to an image-based procedure because the latter may be costly and logistically inconvenient (paragraph 16 of Ellis).

Regarding claim 78, see Figure 7A of Foley.

2. **Claims 1 and 4-18:**

Foley describes a system comprising a detection unit 110 of Figure 1 and subsequently, tracking elements for the system comprise an optical tracking system. Localization element is found in Figure 7. Also included in the system is a processor 114. At least six separate pedicle screws 250 as shown in Figures 12 and 13. These are the first, second, and third members. Each member is illustrated in

Figure 7A as having a fastening portion 250 and an engageable portion (represented by the slots removed from the head of the screws). The localization element provides navigational information for all three members and is illustrated in Figures 7 and 8. A fourth member 360 in Figure 9 engages first, second and third (not shown in Figure 9, *see* Figure 8) members.

However, Foley provides an image based procedure. Ellis teaches that current methods for computer-assisted interventions are based on one of four paradigms. Three out of four of these paradigms are image-based procedures. The remaining one paradigm is an imageless procedure in which tools and tracking devices are attached to a patient in order to guide the intervention free of imaging. See paragraphs 3-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform an imageless procedure, as taught by Ellis, as a well-known alternative to an image-based procedure because the latter may be costly and logistically inconvenient (paragraph 16 of Ellis).

With respect to **Claim 8**, *see* column 9, lines 51-58.

With respect to **Claim 9**, Figure 8 illustrates that when localization occurs, both first and second member will include a localization element extending therefrom.

With respect to **Claim 14**, *see* column 9, lines 38-43.

With respect to **Claim 15-16**, *see* column 4, lines 16-24. The realignment of the vertebrae will also realign the pedicle screws placed in the vertebrae. Also, at column 3, lines 33-36 it is stated that the images are three-dimensional.

Therefore, the processor would align the vertebrae, and subsequently the screws, in three-dimensions.

3. **Claims 22-29:**

Foley describes a system comprising a detection unit 110 of Figure 1, which comprises at least three separate detection device. The multiple detection devices create a sensor array and in turn represent the detection unit. The tracking elements for the system comprise an optical tracking system. Localization element is found in Figure 7. Also included in the system is a processor 114. At least six separate pedicle screws 250 as shown in Figures 12 and 13. These are the first and second members and can be placed in the vertebrae prior to scanning (*see* column 9, lines 46-47). The localization element provides navigational information for both members and is illustrated in Figures 7 and 8. Figure 12 demonstrates the members after implantation. Figure 13 demonstrates the final position of the members after manipulation via probe 280, as shown in Figure 8.

However, Foley provides an image based procedure. Ellis teaches that current methods for computer-assisted interventions are based on one of four paradigms. Three out of four of these paradigms are image-based procedures. The remaining one paradigm is an imageless procedure in which tools and tracking devices are attached to a patient in order to guide the intervention free of imaging. See paragraphs 3-5. It would have been obvious to one having

ordinary skill in the art at the time the invention was made to perform an imageless procedure, as taught by Ellis, as a well-known alternative to an image-based procedure because the latter may be costly and logistically inconvenient (paragraph 16 of Ellis).

With respect to **Claim 28-29**, *see* column 4, lines 16-24. The realignment of the vertebrae will also realign the pedicle screws placed in the vertebrae. Also, at column 3, lines 33-36 it is stated that the images are three-dimensional. Therefore, the processor would align the vertebrae, and subsequently the screws, in three-dimensions.

4. **Claims 33-44 and 47-52:**

Foley describes a system comprising a detection unit 110 of Figure 1 and subsequently, tracking elements for the system comprise an optical tracking system. The tracking element is shown in Figure 7. Also included in the system is a processor 114. At least six separate pedicle screws 250 as shown in Figures 12 and 13. These are the first, second, and fourth members. The tracking element provides navigational information for all three members and is illustrated in Figures 7 and 8. Figures 12 and 13 illustrate the determination of a selected alignment of the first, second and fourth members in relation to each other. A third member 360 in Figure 9 engages first, second and fourth (not shown in Figure 9, *see* Figure 8) members. During insertion, an optically tracked rod inserter can be utilized to guide the third member 360 through the slots of the

first, second and fourth members (*see* column 10, lines 63-67). The rod geometry could also be visible and shown in real-time on monitor 106 as the operator is placing it in the other members (*see* column 11, lines 10-13). Also, the operator can use the computer to determine the required bending angles, or optimal position, of the rod (*see* column 11, lines 3-5).

However, Foley provides an image based procedure. Ellis teaches that current methods for computer-assisted interventions are based on one of four paradigms. Three out of four of these paradigms are image-based procedures. The remaining one paradigm is an imageless procedure in which tools and tracking devices are attached to a patient in order to guide the intervention free of imaging. See paragraphs 3-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform an imageless procedure, as taught by Ellis, as a well-known alternative to an image-based procedure because the latter may be costly and logistically inconvenient (paragraph 16 of Ellis).

With respect to **Claim 38**, the third member would be required to be flexible to allow for the computer to determine a required bend.

With respect to **Claims 43-44**, *see* column 4, lines 16-24. The realignment of the vertebrae will also realign the pedicle screws placed in the vertebrae. Also, at column 3, lines 33-36 it is stated that the images are three-dimensional. Therefore, the processor would align the vertebrae, and subsequently the screws, in three-dimensions.

With respect to **Claim 51**, the positioning of third member does not require further imaging beyond those taken prior to operation due to the optical tracking system (*see* column 11, lines 1-13).

5. **Claims 53-66 and 79:**

Foley describes a system comprising a detection unit 110 of Figure 1 and subsequently, tracking elements for the system comprise an optical tracking system. The tracking element is shown in Figure 7. Also included in the system is a processor 114. At least six separate pedicle screws 250 as shown in Figures 12 and 13. These are the first, second, and fourth members. The tracking element provides navigational information for all three members and is illustrated in Figures 7 and 8. Figures 12 and 13 illustrate the determination of a final orientation of the first, second and fourth members in relation to each other, excluding a third connecting member. The third member 360 in Figure 9 engages first, second and fourth (not shown in Figure 9) members. Figure 8 illustrates a final orientation including the third member. During insertion, an optically tracked rod inserter can be utilized to guide the third member 360 through the slots of the first, second and fourth members (*see* column 10, lines 63-67). The rod geometry could also be visible and shown in real-time on monitor 106 as the operator is placing it in the other members (*see* column 11, lines 10-13). Also, the operator can use the computer to determine the required bending angles, or optimal position, of the rod (*see* column 11, lines 3-5). Since

bending is required, the third member would need to be flexible to allow for the computer to determine a required bend.

However, Foley provides an image based procedure. Ellis teaches that current methods for computer-assisted interventions are based on one of four paradigms. Three out of four of these paradigms are image-based procedures. The remaining one paradigm is an imageless procedure in which tools and tracking devices are attached to a patient in order to guide the intervention free of imaging. See paragraphs 3-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform an imageless procedure, as taught by Ellis, as a well-known alternative to an image-based procedure because the latter may be costly and logistically inconvenient (paragraph 16 of Ellis).

With respect to **Claim 60**, *see* column 4, lines 16-24. The realignment of the vertebrae will also realign the pedicle screws placed in the vertebrae. Also, at column 3, lines 33-36 it is stated that the images are three-dimensional. Therefore, the processor would align the vertebrae, and subsequently the screws, in three-dimensions.

With respect to **Claim 79**, see Figure 7A of Foley.

6. **Claims 67-72:**

Foley describes a system comprising a detection unit 110 of Figure 1, which comprises at least three separate detection device. The tracking elements

for the unit comprise an optical tracking system. The tracking element is found in Figure 7. Also included in the system is a processor 114. At least six separate pedicle screws 250 as shown in Figures 12 and 13. These are the first and second members and can be placed in the vertebrae prior to scanning (*see* column 9, lines 46-47). The localization element provides navigational information for both members and is illustrated in Figures 7 and 8. Figure 12 demonstrates the members after implantation. Figure 13 demonstrates the final position of the members after manipulation via probe 280, as shown in Figure 8.

However, Foley provides an image based procedure. Ellis teaches that current methods for computer-assisted interventions are based on one of four paradigms. Three out of four of these paradigms are image-based procedures. The remaining one paradigm is an imageless procedure in which tools and tracking devices are attached to a patient in order to guide the intervention free of imaging. See paragraphs 3-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform an imageless procedure, as taught by Ellis, as a well-known alternative to an image-based procedure because the latter may be costly and logistically inconvenient (paragraph 16 of Ellis).

With respect to **Claim 71-72**, *see* column 4, lines 16-24. The realignment of the vertebrae will also realign the pedicle screws placed in the vertebrae. Also, at column 3, lines 33-36 it is stated that the images are three-dimensional.

Therefore, the processor would align the vertebrae, and subsequently the screws, in three-dimensions.

7. **Claims 67 and 77:**

In alternative interpretation of Claim 67, Foley describes a system comprising a detection unit 110 of Figure 1, which comprises at least three separate detection device. The tracking elements for the unit comprise an optical tracking system. The tracking element is found in Figure 7. Also included in the system is a processor 114. A first member is illustrated in Figures 2 and 2A-C. The first member comprises four members, or LEDs 122. These LEDs represent the first member's first, third and fourth members. At least six separate pedicle screws 250 are shown in Figures 12 and 13. Any one of these can be considered the second member and can be placed in the vertebrae prior to scanning (*see* column 9, lines 46-47). The tracking element provides navigational information for the second member and is illustrated in Figures 7 and 8. Figure 12 demonstrates the members after implantation. Figure 13 demonstrates the final position of the members after manipulation via probe 280, as shown in Figure 8.

However, Foley provides an image based procedure. Ellis teaches that current methods for computer-assisted interventions are based on one of four paradigms. Three out of four of these paradigms are image-based procedures. The remaining one paradigm is an imageless procedure in which tools and

tracking devices are attached to a patient in order to guide the intervention free of imaging. See paragraphs 3-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform an imageless procedure, as taught by Ellis, as a well-known alternative to an image-based procedure because the latter may be costly and logistically inconvenient (paragraph 16 of Ellis).

8. **Claims 20-21, 31-32, 45-46, 75-76** are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley et al. in view of Ellis, further in view of Acker et al. (US Patent No. 6,332,089). Foley in vie of Ellis is described above in the rejection of claims 1-15, 17-18, 22-30, 33-44, 47-73 and 77. However, the specifics of the imageless display are not provided in these references. Acker discloses a method of performing medical procedures using two or more probes in an imageless environment. The procedure is performed using determined relative dispositions between the probes (*see* column 5, line 55 through column 6, line 8). The display for the invention need not show any image of the patient's tissue (column 12, lines 53-58). Plural probes can be coordinated with one another using information concerning their relative dispositions even without bringing the probes into close proximity to one another (*see* column 16, lines 46-65). *See* column 20, lines 9-64 for a written description of the display represented in Figure 18. Here there is shown icons relating to separate probe and a coordinate system, or atlas map, imposed behind the icons. If previously acquired image data is readily

available and can be registered with the probe position data, the previously acquired image data can be displayed in registration with the indicia (*see* column 12, lines 54-58). Furthermore, column 2, line 57 through column 3, line 14 describes a probe function that can be implemented in an embodiment of Acker's system. The function provides for a probe to map the inner boundaries of the heart, thereby providing contour of a soft tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a method of display and operation of an imageless system, as taught by Acker and illustrated in Figure 18, in order to provide an operator with easy maneuverability and understanding in such an environment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMK

/Brian L Casler/
Supervisory Patent Examiner, Art Unit 3737